



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Health and Environmental Effects Research Laboratory
Research Triangle Park, NC 27711

OFFICE OF RESEARCH AND DEVELOPMENT

June 13, 2019

MEMORANDUM

SUBJECT: Semiannual Animal Facility Inspection Report
FROM: **Exemption 6**
Director, Animal Resources and Research Support
THRU: Michael Narotsky, Chair – NHEERL-Health IACUC *MN*
TO: Wayne Cascio, Institutional Official – NHEERL Animal Program

On May 15, 2019, the semi-annual facility inspection was conducted for the EPA-RTP facilities that house animals or support their care and maintenance. The inspection team consisted of the following IACUC members: Mike Narotsky, Leslie Jarrell, **Exemption 6** **Exemption 6** **Exemption 6** and **Exemption 6** the IACUC Administrator, also participated in the inspection. There were at least two IACUC members present for all USDA animal care and use areas observed.

The summary report was prepared and presented by **Exemption 6** at the IACUC quarterly business meeting on June 13, 2019. The full Committee reviewed and approved the evaluation. There were no minority views regarding the semiannual facility report.

The following facilities were inspected:

- Building A primary housing areas, procedural spaces, and survival surgery areas
- Building A cage wash areas, storage areas, and van used by the Animal Care staff
- Satellite Laboratories in B, E, and H buildings

The inspection team followed animal barrier standard operating procedures and safety principles during the inspection.

The facilities were found to have some potentially significant deficiencies, and many minor deficiencies. Significant deficiencies included the following:

1. A counter top fume hood in the facility QA lab was not within certification. SHEM has worked to get the hood repaired. The hood is now deemed safe for use.
2. Fish tanks need to be rinsed with DI water after cage wash to remove potentially harmful soap residue, allowed to air dry, then stacked for storage. The observed tanks were stacked when wet and there is uncertainty about the regularity of rinsing. This may compromise fish health. New Operating Procedures for cleaning and rinsing tanks should be in place with the change in animal facility operations contract.

3. The power strips in use on some of the fish housing systems may or may not be rated for use around water. The power strips will be reviewed, and unsafe equipment will be replaced. This shouldn't be an immediate safety risk as the power strips are now zip tied to the racks and the tanks are now kept covered, but there is still a safety concern.
4. There was a persistent facility-wide problem of animals with open animal health reports not receiving adequate follow-up care. The AV addressed all open health reports after the inspection, closed many, and made certain there were no animal welfare issues. The lack of adequate care should be addressed when a new vet tech/animal health specialist is brought on board by the new contract.
5. There have been persistent problems with the rabbit care, particularly regarding social housing and basic husbandry. Appropriate caging has been obtained, and the new contract should ensure that the animals are appropriately handled, socially housed and consistently provided with clean food and water in the exercise pen as well as in home cages.
6. Sentinel animals were not appropriately placed with populations of research animals in several instances across floors in the facility. Sentinel animals already held in house were disseminated the week of 5/15, and additional sentinels were obtained and placed with research animals on 5/29. All research populations are now covered by the sentinel program.
 - a. The sentinels being purchased but not placed was particularly concerning due to a coincidental issue with a room of sneezing rats, several of whom have become ill enough to require euthanasia. The sneezing, inflammation and respiratory distress now appears to be treatment related, but the lack of sentinels to determine root cause at the outset was alarming.
7. There have been some overcrowding issues, with cohoused animals growing too large to share space and still meet the requirements of the Guide. The animals were separated. Some instances of overcrowding are still under review by the IACUC. Exceptions to the Guide are considered for pairs cohoused for most of their lives.

The facilities were largely in conformance with US PHS Policy, the *Guide for the Care and Use of Laboratory Animals* (8th Edition) and applicable animal welfare regulations. See the attached table for a detailed listing of the deficiencies and their status regarding correction.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Health and Environmental Effects Research Laboratory
Research Triangle Park, NC 27711

OFFICE OF RESEARCH AND DEVELOPMENT

June 13, 2019

MEMORANDUM

SUBJECT: Semiannual Evaluation of the Animal Care and Use Program

FROM: **Exemption 6** Director, Animal Resources and Research Support *[Signature]*

THRU: Michael Narotsky, Chair – NHEERL-Health IACUC *MN*

TO: Wayne Cascio, Institutional Official – NHEERL Animal Program

Evaluation of the Animal Care and Use Program

The IACUC completed its semiannual evaluation of the institution's animal care and use program on May 8, 2019, in accordance with the 8th edition of the *Guide for the Care and Use of Laboratory Animals (Guide)*, and, as applicable, 9CFR Chapter I, 2.31.

In attendance were: Mike Narotsky, Chair; Leslie Jarrell, Attending Veterinarian; **Exemption 6**
Exemption 6**Exemption 6****Exemption 6** Animal Resources
and Research Support; and **Exemption 6** IACUC Administrator.

The summary report was prepared and presented by **Exemption 6** at the IACUC quarterly business meeting on June 13, 2019. The full Committee reviewed and approved the evaluation as presented. (See attachment). There were no minority views regarding the semiannual program report.

In summary, the committee found the animal program to be consistent with the PHS Policy, the *Guide*, and applicable Animal Welfare Regulations. The significant deficiency concerning adequately trained animal care staff is being addressed with the change in the operations and maintenance contract for the animal facility. No further deficiencies need to be addressed.

Attachments



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Health and Environmental Effects Research Laboratory
Research Triangle Park, NC 27711

OFFICE OF RESEARCH AND DEVELOPMENT

December 6, 2019

MEMORANDUM

SUBJECT: Semiannual Evaluation of the Animal Care and Use Program

FROM: **Exemption 6** Director, Animal Resources and Research Support

Exemption 6
Exemption 6
Exemption 6

THRU: Mike Narotsky, Chair - NHEERL IACUC *MN*

TO: Wayne Cascio, Institutional Official – ORD-RTP Animal Program

Evaluation of the Animal Care and Use Program

The IACUC completed its semiannual evaluation of the institution's animal care and use program on November 26, 2019, in accordance with the 8th edition of the *Guide for the Care and Use of Laboratory Animals (Guide)*, and, as applicable, 9CFR Chapter I, 2.31.

In attendance were: Mike Narotsky, IACUC Chair; Leslie Jarrell, Attending Veterinarian; **Exemption 6** (IACUC Member), **Exemption 6** (IACUC Member), **Exemption 6** (IACUC Member), **Exemption 6** (IACUC Member --SHEM), **Exemption 6** Animal Resources and Research Support (IACUC Member); **Exemption 6** IACUC Administrator and **Exemption 6** Animal Facility Manager.

The summary report was prepared and presented by **Exemption 6** at the IACUC quarterly business meeting on December 3, 2019. The full Committee reviewed and approved the evaluation as presented. (See attachment). There were no minority views regarding the semiannual program report.

In summary, the committee found the animal program to be consistent with the PHS Policy, the *Guide*, and applicable Animal Welfare Regulations. There were no significant deficiencies. Specific details can be found in the attached evaluation checklist.

Attachments

A table is provided, "Semiannual Program Review and Facility Inspection Report," as a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official.

Questions or comments?

Suggestions or comments about this checklist should be e-mailed to: olawdpe@mail.nih.gov.

I. Semiannual Program Review Checklist ⁱ

Institutional Policies and Responsibilities

Date: November 26, 2019

| 1. Animal Care and Use Program ^{NEW} | A* | M | S | C | NA |
|---|----|---|---|---|----|
| • Responsibility for animal well-being is assumed by all members of the program (<i>Guide</i> , p 1) [must] | X | | | | |
| • IO has authority to allocate needed resources (<i>Guide</i> , p 13) | X | | | | |
| • Resources necessary to manage program of veterinary care are provided (<i>Guide</i> , p 14) [must] | X | | | | |
| • Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> (<i>Guide</i> , pp 11, 15) | X | | | | |
| • Program needs are regularly communicated to IO by AV and/or IACUC (<i>Guide</i> , p 13) | X | | | | |
| • Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (<i>Guide</i> , p 14) [must] | X | | | | |
| • Inter-institutional collaborations are described in formal written agreements (<i>Guide</i> , p 15) | | | | | X |
| • Written agreements address responsibilities, animal ownership, and IACUC oversight (<i>Guide</i> , p 15) | | | | | X |
| 2. Disaster Planning and Emergency Preparedness ^{NEW} | A* | M | S | C | NA |
| • Disaster plans for each facility to include satellite locations are in place (<i>Guide</i> , p 35, p 75) [must] <i>There have been improvements to the fish emergency preparedness.</i> | X | | | X | |
| • Plans include provisions for euthanasia (<i>Guide</i> , p 35) [must] | X | | | | |
| • Plans include triage plans to meet institutional and investigators' needs (<i>Guide</i> , p 35) | X | | | | |
| • Plans define actions to prevent animal injury or death due to HVAC or other failures (<i>Guide</i> , p 35) | X | | | | |
| • Plans describe preservation of critical or irreplaceable animals (<i>Guide</i> , p 35) | X | | | | |
| • Plans include essential personnel and their training (<i>Guide</i> , p 35) | X | | | | |
| • Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide</i> , p 35) | X | | | | |
| • Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide</i> , p 35) | X | | | | |
| 3. IACUC ^{NEW} | A* | M | S | C | NA |
| • Meets as necessary to fulfill responsibilities (<i>Guide</i> , p 25) [must] | X | | | | |
| • IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide</i> , p 26) [must] | X | | | | |

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|---|-----------|----------|----------|----------|-----------|
| • Continuing IACUC oversight after initial protocol approval is in place (<i>Guide</i> , p 33) | X | | | | |
| • IACUC evaluates the effectiveness of training programs (<i>Guide</i> , p 15) | X | | | | |
| 4. IACUC Protocol Review - Special Considerations | A* | M | S | C | NA |
| • Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide</i> , p 27) | X | | | | |
| • For pilot studies, a system to communicate with the IACUC is in place (<i>Guide</i> , p 28) | X | | | | |
| • For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide</i> , p 28) | | | | | X |
| • Restraint devices are justified in the animal use protocols (<i>Guide</i> , p 29) [must] | X | | | | |
| • Alternatives to physical restraint are considered (<i>Guide</i> , p 29) | X | | | | |
| • Period of restraint is the minimum to meet scientific objectives (<i>Guide</i> , p 29) | X | | | | |
| • Training of animals to adapt to restraint is provided (<i>Guide</i> , p 29) | X | | | | |
| • Animals that fail to adapt are removed from study (<i>Guide</i> , p 29) | X | | | | |
| • Appropriate observation intervals of restrained animals are provided (<i>Guide</i> , p 29) | X | | | | |
| • Veterinary care is provided if lesions or illness result from restraint (<i>Guide</i> , p 30) [must] | X | | | | |
| • Explanations of purpose and duration of restraint are provided to study personnel (<i>Guide</i> , p 30) | X | | | | |
| • Multiple surgical procedures on a single animal are justified and outcomes evaluated (<i>Guide</i> , p 30) | X | | | | |
| • Major versus minor surgical procedures are evaluated on a case-by-case basis (<i>Guide</i> , p 30) | X | | | | |
| • Multiple survival procedure justifications in non-regulated species conform to regulated species standards (<i>Guide</i> , p 30) | | | | | X |
| • Animals on food/fluid restriction are monitored to ensure nutritional needs are met (<i>Guide</i> , p 31) | X | | | | |
| • Body weights for food/fluid restricted animals are recorded at least weekly (<i>Guide</i> , p 31) | X | | | | |
| • Daily written records are maintained for food/fluid restricted animals (<i>Guide</i> , p 31) | X | | | | |
| • Pharmaceutical grade chemicals are used , when available, for animal-related procedures (<i>Guide</i> , p 31) | X | | | | |
| • Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (<i>Guide</i> , p 31) | X | | | | |
| • Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (<i>Guide</i> , p 32) | | | | | X |

- Disposition plans are considered for species removed from the wild (*Guide*, p 32)
- Toe-clipping only used when no alternative, performed aseptically and with pain relief (*Guide*, p 75)

X
X

5. IACUC Membership and Functions

A* M S C NA

- IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, *IV.A.3.*)
- Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (*Guide*, p 24)ⁱⁱ
- IACUC authority and resources for oversight and evaluation of institution's program are provided (*Guide*, p 14)
- IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, *IV.B.*)
- Conducts semiannual inspections of institutional animal facilities (PHS Policy, *IV.B.*)
- IACUC organizationally reports to the Institutional Official (PHS Policy, *IV.A.1.b.*)
- Methods for reporting and investigating animal welfare concerns are in place (*Guide*, p 23) **[must]**
- Reviews and investigates concerns about animal care and use at institutionⁱⁱⁱ (PHS Policy, *IV.B.*)
- Procedures are in place for review, approval, and suspension of animal activities^{iv} (PHS Policy, *IV.B.*)
- Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, *IV.B.*)
- Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (*Guide*, p 27-32)
- Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS^v (*Guide*, p 30) **[must]**

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6. IACUC Training ^{NEW}

A* M S C NA

- All IACUC members should receive:
 - Formal orientation to institution's program (*Guide*, p 17)
 - Training on legislation, regulations, guidelines, and policies (*Guide*, p 17)
 - Training on how to inspect facilities and labs where animal use or housing occurs (*Guide*, p 17)
 - Training on how to review protocols as well as evaluate the program (*Guide*, p 17)
 - Ongoing training/education (*Guide*, p 17)

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7. IACUC Records and Reporting Requirements^{vi}

A* M S C NA

- Semiannual report to the IO (PHS Policy, *IV.B.*)
 - Submitted to IO every 6 months

X

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|--|-----------|----------|----------|----------|-----------|
| ○ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies) | X | | | | |
| ○ Includes minority IACUC views there were none during this review period; otherwise would be included. | X | | | | X |
| ○ Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure ^{vii} | X | | | | |
| ○ Distinguishes significant from minor deficiencies | X | | | | |
| ○ Includes a plan and schedule for correction for each deficiency identified ^{viii} | X | | | | |
| • Reports to OLAW (PHS Policy, <u>IV.F.</u>) | | | | | |
| ○ Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views | X | | | | |
| ○ Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance (<u>NOT-OD-05-034</u>) | X | | | | |
| ○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (<u>NOT-OD-05-034</u>) | X | | | | |
| • Reports to U.S. Department of Agriculture (USDA) or Federal funding agency ^{ix} | | | | | |
| ○ Annual report to USDA contains required information including all exceptions/exemptions | X | | | | |
| ○ Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards there were none during this review period; otherwise would be included. | | | | | X |
| ○ Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies there were none during this review period; otherwise would be included. | | | | | X |
| ○ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency | X | | | | |
| • Records (PHS Policy, <u>IV.E.</u>) | | | | | |
| ○ IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years | X | | | | |
| ○ Records of IACUC reviews of animal activities include all required information ^x | X | | | | |
| ○ Records of IACUC reviews are maintained for 3 years after the completion of the study | X | | | | |
| 8. Veterinary Care (See also next section - Veterinary Care) | A* | M | S | C | NA |
| • An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care ^{xi} | X | | | | |
| • Veterinary access to all animals is provided (<i>Guide</i> , p 14) [must] | X | | | | |
| • Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (<i>Guide</i> , p 14) [must] | X | | | | |
| • Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (<i>Guide</i> , p 5) [must] | X | | | | |
| • Veterinarian provides consultation when interventional control is not possible (<i>Guide</i> , p 5) [must] | X | | | | |

- If part time /consulting veterinarian, visits meet programmatic needs (*Guide*, [p 14](#))
- Regular communication occurs between veterinarian and IACUC (*Guide*, [p 14](#))
- Veterinarian(s) have experience and training in species used (*Guide*, [p 15](#)) **[must]**
- Veterinarian(s) have experience in facility administration/management (*Guide*, [p 15](#))

9. Personnel Qualifications and Training

- All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: **[must]**
 - Veterinary/other professional staff (*Guide*, p 15-16)
 - IACUC members (*Guide*, p 17)
 - Animal care personnel (*Guide*, p 16) **Training is being provided**
 - Research investigators, instructors, technicians, trainees, and students (*Guide*, pp 16-17)
- Continuing education for program and research staff provided to ensure high quality care and reinforce training (*Guide*, pp 16-17) **New training is being provided**
- Training is available prior to starting animal activity (*Guide*, p 17)
- Training is documented (*Guide*, p 15)
- Training program content includes: (*Guide*, p 17)
 - Methods for reporting concerns (*Guide*, p 17)
 - Humane practices of animal care (e.g., housing, husbandry, handling) ^{xii}
 - Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (*Guide*, p 17)^{xiii})
 - Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)
 - Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)
 - Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (*Guide*, p 20)
 - Animal care and use legislation (*Guide*, p 17)
 - IACUC function (*Guide*, p 17)
 - Ethics of animal use and Three R's (*Guide*, p 17)

10. Occupational Health and Safety of Personnel

- Program is in place and is consistent with federal, state, and local regulations (*Guide*, p 17) **[must]**

- | | | |
|---|---|---|
| • Program covers <i>all</i> personnel who work in laboratory animal facilities (<i>Guide</i> , p 18) | X | |
| • Changing, washing, and showering facilities are available as appropriate (<i>Guide</i> , p 19) | X | |
| • Hazardous facilities are separated from other areas and identified as limited access (<i>Guide</i> , p 19) | X | |
| • Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (<i>Guide</i> , p 20) <i>New processes are in place for animal care staff involved with technical service requests.</i> | X | X |
| • Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (<i>Guide</i> , p 20) | X | |
| • Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (<i>Guide</i> , p 21) | X | |
| • Personal Protective Equipment for the work area is appropriate and available (<i>Guide</i> , p 21) | X | |
| • Program for medical evaluation and preventive medicine for personnel includes: | | |
| ○ Pre-employment evaluation including health history (<i>Guide</i> , p 22) | X | |
| ○ Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (<i>Guide</i> , p 22) | X | |
| ○ Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (<i>Guide</i> , p 23) | X | |
| ○ Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (<i>Guide</i> , p 23) | X | |
| ○ Promotes early diagnosis of allergies including preexisting conditions (<i>Guide</i> , p 22) | X | |
| ○ Considers confidentiality and other legal factors as required by federal, state and local regulations (<i>Guide</i> , p 22) <i>must</i> | X | |
| ○ If serum samples are collected, the purpose is consistent with federal and state laws (<i>Guide</i> , p 22) <i>must</i> <i>Serum is not collected</i> | | X |
| • Waste anesthetic gases are scavenged (<i>Guide</i> , p 21) | X | |
| • Hearing protection is provided in high noise areas (<i>Guide</i> , p 22) <i>Protection is provided, but there are no high noise areas requiring protection.</i> | X | X |
| • Respiratory protection is available when performing airborne particulate work (<i>Guide</i> , p 22) | X | |
| • Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include: | | |
| ○ Tuberculosis screening provided for all exposed personnel (<i>Guide</i> , p 23) | | X |
| ○ Training and implementation of procedures for bites, scratches, or injuries associated with macaques (<i>Guide</i> , p 23) | | X |
| ○ PPE is provided including gloves, arm protection, face masks, face shields, or goggles (<i>Guide</i> , p 21) | | X |
| ○ Injuries associated with macaques are carefully evaluated and treatment implemented (<i>Guide</i> , p 23) | | X |
| • Occupational safety and health of field studies is reviewed by OSH committee or office | | X |

(Guide, p 32)

11. Personnel Security ^{NEW}

- Preventive measures in place include pre-employment screening, and physical and IT security (Guide, p 23)

A* M S C NA
X

12. Investigating & Reporting Animal Welfare Concerns ^{NEW}

- Methods for investigating and reporting animal welfare concerns are established (Guide, p 23) **must**
- Reported concerns and corrective actions are documented (Guide, p 24)
- Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (Guide, p 24)
 - Includes multiple contacts (Guide, p 24)
 - Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (Guide, p 24)

A* M S C NA
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X

* **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

NOTES:

Notes are included in the body of the checklist, in *italic and blue highlighter*

Veterinary Care

Date:

1. Clinical Care and Management ^{NEW}

| | A* | M | S | C | NA |
|---|----|---|---|---|----|
| • Veterinary program offers high quality of care and ethical standards (<i>Guide</i> , p 105) [must] | X | | | | |
| • Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (<i>Guide</i> , p 106) | X | | | | |
| • Veterinarian provides oversight to surgery and perioperative care (<i>Guide</i> , p 106) | X | | | | |
| • Veterinary care program is appropriate for program requirements (<i>Guide</i> , pp 113-114) | X | | | | |
| • Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (<i>Guide</i> , p 114) | X | | | | |
| • Procedures to triage and prioritize incident reports are in place (<i>Guide</i> , p 114) | X | | | | |
| • Procedures are in place to address: <ul style="list-style-type: none"> ○ Problems with experiments to determine course of treatment in consultation with investigator (<i>Guide</i>, p 114) ○ Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (<i>Guide</i>, p 114) ○ Veterinary review and oversight of medical and animal use records (<i>Guide</i>, p 115) | X | | | | |
| • Procedures established for timely reporting of animal injury, illness, or disease (<i>Guide</i> , p 114) [must] | X | | | | |
| • Procedures established for veterinary assessment, treatment, or euthanasia (<i>Guide</i> , p 114) [must] | X | | | | |
| • Veterinarian is authorized to treat, relieve pain, and/or euthanize (<i>Guide</i> , p 114) [must] | X | | | | |

2. Animal Procurement and Transportation/Preventive Medicine

| | A* | M | S | C | NA |
|--|----|---|---|---|----|
| • Procedures for lawful animal procurement are in place (<i>Guide</i> , p 106) [must] | X | | | | |
| • Sufficient facilities and expertise are confirmed prior to procurement (<i>Guide</i> , p 106) | X | | | | |
| • Procurement is linked to IACUC review and approval (<i>Guide</i> , p 106) | X | | | | |
| • Random source dogs and cats are inspected for identification (<i>Guide</i> , p 106) | | | | | X |
| • Population status of wildlife species is considered prior to procurement (<i>Guide</i> , p 106) | | | | | X |
| • Appropriate records are maintained on animal acquisition (<i>Guide</i> , p 106) | X | | | | |
| • Animal vendors are evaluated to meet program needs and quality (<i>Guide</i> , p 106) | X | | | | |
| • Breeding colonies are based on need and managed to minimize numbers (<i>Guide</i> , p 107) | X | | | | |

- Procedures for compliance with animal transportation regulations, including international requirements, are in place (*Guide*, p 107) **[must]**
- Transportation is planned to ensure safety, security and minimize risk (*Guide*, p 107)
- Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (*Guide*, pp 107- 108)
- Appropriate loading and unloading facilities are available (*Guide*, p 109)
- Environment at receiving site is appropriate (*Guide*, p 109)
- Policies in place on separation by species, source, and health status (*Guide*, pp 109, 111-112)
- Procedures in place for quarantine to include zoonoses prevention (*Guide*, p 110)
- Quarantined animals from different shipments are handled separately or physically separated (*Guide*, p 110)
- Procedures in place for stabilization/acclimation (*Guide*, pp 110-111)
- Policies in place for isolation of sick animals (*Guide*, p 112)
- Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (*Guide*, p 112)
- Diagnostic resources are available for preventive health program (*Guide*, p 112)

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3. Surgery

A* M S C NA

- Surgical outcomes are assessed and corrective changes instituted (*Guide*, p 115)
- Researchers have appropriate training to ensure good technique (*Guide*, p 115) **[must]**
- Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (*Guide*, p 116)
- Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (*Guide*, p 116)
- Surgical procedures including laparoscopic procedures are categorized as major or minor (*Guide*, pp 117-118)
- For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (*Guide*, p 118)
- Aseptic technique is followed for survival surgical procedures (*Guide*, pp 118-119)
- Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (*Guide*, p 119) **Procedures have been updated to include sterility indicators inside the surgical packs as well as on the outside.**
- Procedures for monitoring surgical anesthesia and analgesia are in place (*Guide*, p 119)
- For aquatic species, skin surfaces are kept moist during surgical procedures (*Guide*, p 119)
- Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin

X
X
X
X
X
X
X
X
X
X
X

X

X

closures) (*Guide*, pp 119-120)

4. Pain, Distress, Anesthesia and Analgesia

- Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (*Guide*, p 121)
- Selection of analgesics and anesthetics is based on professional veterinary judgment (*Guide*, p 121)
- Painful procedures are monitored to ensure appropriate analgesic management (*Guide*, p 122)
- Nonpharmacologic control of pain is considered as an element of postprocedural care (*Guide*, p 122)
- Procedures are in place to assure antinoception before surgery begins (*Guide*, p 122) **[must]**
- Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (*Guide*, p 122)
- Special precautions for the use of paralytics are in place to ensure anesthesia^{xiv} (*Guide*, p 123)

A* M S C NA

X

X

X

X

X

X

X

5. Euthanasia

- Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (*Guide*, p 123)
- Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (*Guide*, pp 123-124)
- Training is provided on appropriate methods for each species and considers psychological stress to personnel (*Guide*, p 124)
- Procedures and training are in place to ensure death is confirmed (*Guide*, p 124) **[must]**

A* M S C NA

X

X

X

X

6. Drug Storage and Control ^{NEW}

- Program complies with federal regulations for human and veterinary drugs (*Guide*, p 115) **[must]** *All procedures were updated following a DEA audit.*
- Drug records and storage procedures are reviewed during facility inspections (*Guide*, p 115)
- Procedures and policies are in place to ensure analgesics and anesthetics are used within expiration date (*Guide*, p 122) **[must]**
- Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (*Guide*, p 122)

A* M S C NA

X

X

X

X

* A = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy IV.A.1.a.i.) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

ⁱ The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

ⁱⁱ Part 2 Subpart C - Research Facilities

- 2.31(b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

ⁱⁱⁱ 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

^{iv} 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

^v 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

^{vi} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^{vii} 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

^{viii} 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

^{ix} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^x In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:

2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

2.31(d)(1)(iii) - "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

2.31(d)(1)(iv) - "Procedures that may cause more than momentary or slight pain or distress to the animals will:

- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;"

2.31(d)(1)(x) - “No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing...”

^{xi} 2.33(a)(1) - “In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility.” [USDA requirement additional]

^{xii} 2.32(c) - “Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures.”

^{xiii} 2.32(c) - additional specifications include:

- “proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility”
- “methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility...”
- “utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research , that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act.” [USDA training specifications are more detailed than PHS Policy].

^{xiv} 2.31(d)(iv)(C) - “Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia.”



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Health and Environmental Effects Research Laboratory
Research Triangle Park, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

December 6 , 2019

MEMORANDUM

SUBJECT: Semiannual Animal Facility Inspection Report

FROM: **Exemption 6**
Director, Animal Resources and Research Support

TO: Michael Narotsky, Chairman *MN*
IACUC

On November 13, 2019, the semi-annual facility inspection was conducted for the EPA-RTP facilities that house animals or support their care and maintenance. The inspection team consisted of the following IACUC members: **Exemption 6** **Exemption 6** **Exemption 6** **Exemption 6** **Exemption 6** **Exemption 6** the IACUC Administrator, and **Exemption 6** Animal Ordering Officer, also participated in the inspection. There were at least two IACUC members present for all USDA animal care and use areas observed.

The summary report was prepared and presented by **Exemption 6** at the IACUC quarterly business meeting on December 3, 2019. The full Committee reviewed and approved the evaluation. There were no minority views regarding the semiannual facility report.

The following facilities were inspected:

- Building A primary housing areas, procedural spaces, and survival surgery areas
- Building A cage wash areas and storage areas

The inspection team followed animal barrier standard operating procedures and safety principles during the inspection.

There were no significant deficiencies

The facilities were in conformance with US PHS Policy, the *Guide for the Care and Use of Laboratory Animals* (8th Edition) and applicable animal welfare regulations. See the attached table for a detailed listing of the deficiencies and their status regarding correction.

Health | ACUC SemiAnnual Facility Inspection Report - 11-13-2019

Team 1: **Exemption 6** **Exemption 6** **Exemption 6** (1st floor, 2nd floor, and 3rd floor)

Team 2: **Exemption 6** **Exemption 6** **Exemption 6** **Exemption 6**

| Location | Deficiency | Minor/Significant/NA | Responsible Party |
|------------|--|--|--|
| A199-E | OX BOW Critical Care, lot # 180223 - expired (best by Oct 2019) | NA | ACS. Resolved immediately |
| A199-E | Lab Diet Teklad - Envigo - date on bag 071119M #7022 (not sure if this is milling date or expiration date) | NA | ACS. Resolved immediately |
| A199-E | Lab Diet with date Sept 12 #0362 | NA | ACS. Resolved immediately |
| A198 | Waste Bottle needs Hazardous label, secondary containment, and list waste on sheet of paper | Minor | ACS. Resolved immediately |
| A198 | Liquid should not be stored above bench height | Minor | ACS |
| A198 | Update the QC lab sign on the door | Minor | SHEM fixed 11/19 |
| A198 | Formalin needs secondary containment | Minor | ACS. Resolved before 12/19 |
| A197 | Fire Extinguisher needs 18" of egress & needs sign | Minor | ACS. Resolved immediately |
| A197 | Warning hot surface sign needs to be removed | Minor | ACS |
| A195 | Fire Extinguisher needs 18" of egress & needs sign | Minor | ACS. Resolved immediately |
| A196H | Needs contact information | Minor | ACS |
| A197 | Emergency Push button needs to be re-made on tunnel washer | Minor | SHEM and ACS working on this |
| A197 | Sheila Shine needs a new label | Minor | ACS |
| A197 | Move trash bins, blocking control panels | Minor | ACS. Resolved immediately |
| A197 | Remove cardboard | Minor | ACS working on this. Ongoing process |
| A197 | Remove clutter (old cages & Fish bucket) | Minor | ACS working on this. Ongoing process |
| A192 | Ceiling tile out | Minor | Wood |
| A299 | (north & south) Door signs need new tape (Stop sign loose on one side) | Minor | ACS |
| A299-C | Stencil printed information for "Fire Damper" reads "Fike Camper" | Minor | Wood |
| A299-D | Walls inside closet is painted plywood | Minor | Wood |
| A258-A | Shower not certified in October | Minor | Resolved November |
| A258-A | Sani-Cloth expired 11/2014 and 11/2010 | Minor | Exemption 6 Exemption 6 Exemption 6 |
| A251-A | No dates on betadine or Lvanio plastic liquid on work station, un-labeled spray bottle, expired surgical gloves (ALL corrected by Exemption 6) | Minor | Exemption 6 Exemption 6 |
| A256 | Eye wash not certified in October | Minor | Resolved November |
| A261-A | Eye wash/shower station BLOCKED - coolers/buckets and boxes are inside the area designated for the eye-wash station | Repeat SHEM issues. PI has been contacted on multiple occasions. | Exemption 6 Exemption 6 Exemption 6 |
| A261-A | No dates on liquid containers inside the surgery stations in satellite facility - floors dirty and area cluttered in testing room A261-C | Same as above | Exemption 6 Exemption 6 Exemption 6 |
| A261-A | Incompatible and expired chemicals stored together - Flammable chemical sitting on top of the flammable cabinet | Same as above | Exemption 6 Exemption 6 Exemption 6 |
| A261-A | Lots of expired chemicals - to many to individually name! | Same as above | Exemption 6 Exemption 6 Exemption 6 |
| A261-A | Sani-Cloth Wipes on the counter expired 07/2017 | Same as above | Exemption 6 Exemption 6 Exemption 6 |
| A261-A | Tissue / samples on counter not labeled | Same as above | Exemption 6 Exemption 6 Exemption 6 |
| A261-A | Ziplock bags of food on the floor (1-pink, 1-beige) not labeled | Same as above | Exemption 6 Exemption 6 Exemption 6 |
| A261-A | Jug labeled 0.3% /TBS-X (w/ initials CR) and 8/12 - not sure of exact date | Same as above | Exemption 6 Exemption 6 Exemption 6 |
| A277 | Exit door to hallway (parking lot side) will not close by itself - must be pushed to close | Minor | Service call 11/19 |
| 280-A | Rusty Ring Stand (sited at last inspection) needs to be removed from the room and thrown away | Minor | Exemption 6 |
| 280-A | Inside hood - to many items against the back of hood blocking the back draft, Formalin expired 8/19, Isopropanol expired 4/19 | Minor | ACS |
| 280-A | Artemia water culture in spray bottle has no date | Minor | ACS |
| 280-A | Gemma micro food in door of frig expired 10/11/2019 (in Ziplock bag) | Minor | ACS |
| 280-A | Food refrigerator temp probe is not cold enough and has unusual reading Exemption 6 inside frig temp is 54.14F, 12.3C should be 3-4C | Minor | ACS |
| 280-suite | LaMotte Chlorine kit waste on 2nd shelf of cart should be in secondary containment by SHEM regulations | Minor | ACS |
| 280-suite | pH 10 buffer on 2nd shelf of cart expired | Minor | ACS |
| A280-E | (Rack #5) Electric cord on temp prob needs to be zip tied to rack | Minor | ACS |
| A280-E | (Rack #4) electrical box on top needs to be zip tied to top of rack | Minor | ACS |
| A280-E | All electrical cords in room need to be pulled up tight and zip tied to keep them higher and off floor | Minor | ACS |
| A280-G | All electrical cords in room need to be pulled up tight and zip tied to keep them higher and off floor | Minor | ACS |
| All Suites | On the Signage "Primary Enclosures and Animal Space Provisions" has incorrect fish information listed | Minor | Exemption 6 |
| A390-C | Empty CO2 tank | Minor | ACS |
| A390-B | In Flammable cabinet - Isothesia expired 1/31/2019 | Minor | ACS will discard, since there is no clear owner |
| A390-C | Hematoxylin stain under sink - no date | Minor | same as above |
| A390-D | Under cabinet 70% Isopropyl date 12/17 (2 full bottles 1 partial) | Minor | same as above |
| A390-D | Avagard foaming expiration date 6/2017 | Minor | same as above |
| A390-D | .09% Sodium Chloride expiration date 4/1/2018 (3 bottles) | Minor | same as above |
| A390-D | several boxes of needles and syringes with expired dates | Minor | same as above |

| | | | |
|------------|--|--|--|
| A386-C | Light cover broken | Minor | Service call 11/19 |
| A399-C | Trash on floor | Minor | Who is servicing the DI water these days? They need to clean up. |
| A380-A | No soap at sink | Minor | ACS |
| A380-A | Santi Cloths expired 2017 | Minor | ACS |
| A377-suite | No soap or paper towels at sink | Minor | ACS |
| A399 | South door sign not on wall | Minor | ACS |
| A376-A | Cart in suite has no Santi cloth wipes | Minor | ACS |
| A476G | Original Cage cards have been removed | Minor | Exemption 6 |
| A476C | Original Cage cards have been removed | Minor | Exemption 6 |
| A477C | Needs contact information | Minor | Exemption 6 |
| A479G | BSC not working, needs new filter | Minor | SHEM -- in process |
| A479A | Panel is removed, please replace | Minor | Exemption 6 |
| A479A | (Yellow Bucket)Info on card needs to be filled out | Minor | ACS |
| A479A | White shades/shower curtains falling apart | Minor | Exemption 6 |
| A490 | Expired Hand soap | Minor | |
| A499C | Remove box with equipment | Minor | Wood |
| A486 | Need card for Hay Bucket | Minor | ACS-fixed 11/19 |
| A486 | Need card for Orchard Grass | Minor | ACS-fixed 11/19 |
| A486B | Needs contact information | Minor | |
| A492B | Needs phone list | Minor | ACS |
| A489 | Remove "high voltage box" / scientific equipment (no one is sure what it is, or when it was last used) | Minor | Exemption 6 |
| A490D | Rabbit Catherers expired | Minor | ACS-fixed 12/19 |
| A490 | Ice Machine is broken | Minor | Service call 11/19 |
| A490 | Hose for CO2 needs to be replaced | Minor | Puckett |
| A490 | Lid needs to be replaced (cracked) | Minor | ACS |
| A576 | Sink not working | Minor | Service call 11/19 |
| A580 | No Sentinels in the room | Minor | ACS -- resolved before 12/19 |
| A577F | Needs new emergency contact information | Minor | fixed 11/19 |
| A580 | NuAire BSC no certified since Yr 2014 | Ongoing -- part of replacement project | will be replaced |
| A580 | Remove ladder | Minor | Wood (called again 12/5/19) |
| A584 | Remove mop bucket-blocking eye wash and emergency shower | Minor | fixed 11/19 |
| A584 | Replace bulb for steris light | Minor | ACS provided with bulbs 12/5/19 |
| A584 | Replace Yellow CO2 Euthanasia Guideline sign | Minor | ACS |
| A584 | Respirators need to be stored in a sealed bag | Minor | ACS or PI |
| A588 | Parking lot side-sprinkler housing needs to be flush, outside Room A585 | Minor | SHEM |
| A592 | No sign of phone numbers | Minor | fixed 11/19 |
| A587 | Waste container needs proper bag size | Minor | fixed 11/19 |
| A587 | Lid to CO2 chamber is cracked | Minor | fixed 11/19 |
| A587 | Water bath does not have a date when last cleaned. | Minor | ACS |
| A587 | Troemner weights, not audited | Minor | Will audit 2020 |